



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

JUN 10 1999

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Mr. Alexander S. Mathews  
Animal Health Institute  
501 Wythe Street  
Alexandria, Virginia 22314-1917

Re: Citizen Petition 98P-1123/CP

Dear Mr. Mathews:

This is an interim response to the citizen petition (98P-1123/CP) which you submitted to the Food and Drug Administration (FDA) on behalf of the Animal Health Institute (AHI) on December 2, 1998. The citizen petition requests FDA to immediately suspend requests of sponsors of pending and approved New Animal Drug Applications (NADAs) for antibacterial animal drugs to commit to conducting post-approval antibacterial susceptibility monitoring programs targeting food borne pathogens (including "surrogate organisms") as a condition of approval or continued approval of such NADAs. This requested suspension would be in effect until such time as a final regulation for such testing and reporting under 21 U.S.C. 360b(1) is promulgated in accordance with 21 U.S.C. 371(a).

According to the administrative regulations at 21 CFR 10.30, FDA is required to respond to a citizen petition within 180 days. FDA is currently considering the issues raised in your citizen petition and the comments to the agency's discussion paper entitled "A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals" (the framework) 64 FR 887, January 6, 1999. Because of the complex nature of the action requested, which requires careful and thorough scientific, legal, and policy consultation, analysis and coordination within the agency, FDA will require additional time to issue a final response to your citizen petition.

FDA will issue a final response to your citizen petition upon completion of our analysis of the comments received on the framework document, numerous consultations and resolution of the scientific, legal and policy issues involved.

Sincerely yours,

Stephen F. Sundlof, D.V.M., Ph.D  
Director, Center for Veterinary Medicine

98P-1123

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